EXHIBIT T

NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

2016

ORGANIZATIONAL LAW

LICENSING LAW

DRUG LAW

CENSUS DATA

Survey *of* Pharmacy Law

Including all 50 states, DC, Guam, and Puerto Rico

Survey of Pharmacy Law – 2016

Editor and Publisher
National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056
www.nabp.net

Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary

The information contained in the NABP *Survey of Pharmacy Law* is furnished by the individual state boards of pharmacy. The National Association of Boards of Pharmacy is not responsible for the accuracy of the information.

Previous editions of the *Survey of Pharmacy Law* were produced in a printed format from 1950 through 2002. The 2003 through 2016 editions of the *Survey of Pharmacy Law* were each produced as a CD.

19. Drug Product Selection Laws

State	State Drug Formulary	Two-line Rx Format	Permissive or Mandatory*	How to Prevent Substitution	Cost Savings Pass-on	Patient Consent**
Alabama	None	Yes	P, BBB	A	U	No
Alaska	None	No	P	B	T	Yes
Arizona	None	No	P	I	U	Yes
Arkansas	None	No	P	B	T	Yes
California	None	No	P	EE	T	Yes
Colorado	None	No	P	J	S	Yes GGG
Connecticut	None	No	P	E, F	S	Yes
Delaware	None	No	P	E	S	Yes
District of Columbia	Positive	No	P	B	T	Yes
Florida	Negative L	No	M	B	S	Yes
Georgia	None	No	P	C	N	Yes
Guam	None	No	P	G	T	No DD
Hawaii	Positive K, AA	No	P	CC, PP	T	Yes
Idaho	None	No	P	WW	U	No
Illinois	Positive KK	No	P	AAA	T	No YY
Indiana	None	Yes	P	A	O	Yes II
Iowa	None	No	P	I	X	Yes
Kansas	None	Yes FFF	M	A, I	T	Yes II
Kentucky	Negative	Yes (conditional)	M	B, H, Y	T	Yes
Louisiana	None K	No	P	R	HH	Yes
Maine	None	No	P	B, R	V	Yes
Maryland	None K	No	P	H, I	HH	Yes
Massachusetts	Positive K	No	M	B	T	No
Michigan	None	No	P	E	S	No
Minnesota	Negative	No	M	E	S	Yes
Mississippi	None	Yes	M	A	T	Yes
Missouri	None	Yes	P	A	T	No
Montana	None	No	P	CCC	S, T	Yes
Nebraska	Positive K	No	P	B	U	No
Nevada	Positive K	No	M	B	T	No
New Hampshire	Positive K	No	P	B	T	Yes
New Jersey	Positive	Yes	M	A	T	No
New Mexico	None	No	P	G	S	No
New York	Positive	No Z	M	D, H	T	Yes
North Carolina	None	Yes (optional)	P	A, B	T	Yes UU
North Dakota	None	No Z	P	B	T	Yes
Ohio	None	No	P	E	T	Yes
Oklahoma	None	No	W	W	U	W
Oregon	None	No	P	ZZ	T	No
Pennsylvania	None K	No	M	C	T	Yes
Puerto Rico	None	No	M	LL	T	Yes
Rhode Island	None JJ	No	M, DD	C, GG	S	No
South Carolina	None	Yes	P	A	U	Yes
South Dakota	None K	No	P	B	U	Yes
Tennessee	None	No	P	TT	S	No
Texas	None K	No	P	CC	T	Yes
Utah	Positive K	Optional	P	B, Q	U	Yes
Vermont	None K	No	M	FF	V	Yes
Virginia	None K	No	P	H	T	Yes
Washington	None	Yes	M	A	BB	No DD
West Virginia	K	No Z	B, M, O, HH	B, F, CC	S	Yes
Wisconsin	Positive K	No	P	B	HH	Yes
Wyoming	None K	No	P	I	T	No

* State laws either permit the pharmacist to substitute or mandatorily require the pharmacist to substitute a generic version of the prescribed drug if all prescription requirements are met.

** Yes – Includes states where consent is required and those that require the patient to be notified/informed of substitution.

Colored text denotes change from 2015 edition.

19. Drug Product Selection Laws (cont.)

State	Has State Designated a List of Drugs That Are Not Substitutable (ie, Narrow Therapeutic Index Drugs)?	Does State Have Any Interchangeability Requirements for Biosimilars/Biologics?
Alabama	No	No
Alaska	No	No
Arizona	No K	No
Arkansas	No K	No EEE
California	No	No
Colorado	No	Yes
Connecticut	No	No
Delaware	K	Yes HHH
District of Columbia	No	No
Florida	Yes	No HHH
Georgia	No	—
Guam	—	—
Hawaii	Yes PP	Yes SS
Idaho	Yes	No
Illinois	No	No HHH
Indiana	No	No
Iowa	No	No
Kansas	K	Yes SS
Kentucky	Yes QQ	No
Louisiana	No K	Yes
Maine	Yes B, R	No
Maryland	No	No
Massachusetts	No MM	Yes K, MM
Michigan	No	—
Minnesota	Yes NN	No
Mississippi	No	No
Missouri	No	KKK
Montana	No	No
Nebraska	No	Yes III
Nevada	No	No
New Hampshire	No	No
New Jersey	No	No
New Mexico	No	No
New York	No	No
North Carolina	Yes VV	Yes HHH
North Dakota	No	Yes HHH
Ohio	No	No
Oklahoma	No	No
Oregon	No	Yes HHH
Pennsylvania	Yes	Yes
Puerto Rico	K	—
Rhode Island	Yes RR	—
South Carolina	No	No
South Dakota	No	No DDD
Tennessee	No XX	No
Texas	No OO	Yes LLL
Utah	No	Yes
Vermont	No	No
Virginia	No	Yes JJJ
Washington	No	No
West Virginia	No	No K
Wisconsin	No	Yes SS
Wyoming	No	No

Colored text denotes change from 2015 edition.
— Indicates information is not available.

19. Drug Product Selection Laws (cont.)

LEGEND

A — Prescriber's signature on appropriate line of two-line prescription.

B — To prevent DPS, prescriber must expressly indicate in some manner. (AK, AR, SD – Prescriber must write in own handwriting in addition to signature "Brand Necessary." MA – Must indicate "No Substitution." ND – Prescriber must write in own handwriting in addition to signature "Brand Medically Necessary." NH – The prescribing practitioner handwrites "medically necessary" on each paper prescription, or uses electronic indications when transmitted electronically, or gives instructions when transmitted orally that the brand-name drug product is medically necessary. NV – Prescriber must write in own handwriting "Dispense as Written.")

C — Prescriber's signature shall validate the prescription and, unless the prescriber handwrites (RI – Indicates) "Brand Necessary" or "Brand Medically Necessary," shall designate approval of drug substitution by the pharmacist.

D — Prescriber must indicate "Dispense as Written" in the designated box, or positively indicate brand for electronic prescriptions.

E — Prescriber must write in own handwriting: "DAW" or "Dispense as Written." (DE – "Brand necessary" or "brand medically necessary." MN – Unless the prescription is transmitted electronically in accordance with the Code of Federal Regulations, Title 42, Section 423.)

F — Prescriber indicates "Medically Necessary" in own handwriting.

G — A licensed practitioner shall prohibit drug product selection by handwriting the words "No Substitution" or the diminutive "No Sub" on the face of the prescription.

H — "Brand Medically Necessary" to be handwritten on the face of the prescription by the prescriber for Medicaid patients, or product selection is allowed. (NY – An alternative provision that requires positive indication for electronic prescriptions. VA – For all non-Medicaid patients, phrase must be included, but not required to be handwritten.)

I — Prescriber must expressly indicate that substitution is not allowed.

J — Prescriber must handwrite "Dispense as Written" or hand initial a preprinted box labeled "Dispense as Written." May also be done electronically.

K — Uses FDA Therapeutic Equivalency List ("Orange Book"). (HI – Plus deletions and additions by the Drug Product Selection Board administered by the Department of Health, Food and Drug Branch. KS – Uses Orange Book – National Formulary as official compendium. KSA 65-656. LA – Plus FDA "Purple Book" for biosimilar/ biological products. MA – Plus "additional list" and "exception list." PA – Plus narrow therapeutic index.)

L — Each pharmacy is to develop DPS List.

M — Mandatory.

N — The pharmacist shall dispense the lowest retail priced drug product that is in stock, and which, in the pharmacist's opinion, is pharmaceutically and therapeutically equivalent to the prescribed drug.

O — Unless in the pharmacist's professional judgement.

P — Permissive. (AL – If authorized by prescriber.)

Q — Allows use of preprinted "Do Not Substitute" checkbox.

R — Box must be checked to prevent DPS.

S — Full savings must be passed on to consumer.

T — Drug dispensed must be less or no more expensive than drug prescribed. (IL – Refer to 225 ILCS 85/25.)

U — No cost savings pass-on requirement mentioned.

V — No more than usual and customary charge for prescribed drug.

W — O.S. (1961) states that it is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser.

X — Must pass on 50% of difference between brand name cost and generic cost.

Y — May indicate in manner of his or her choice on the prescription "Do Not Substitute," except that the indication shall not be preprinted on a prescription.

Z — One-line format.

AA — Product selection laws under jurisdiction of Department of Health, Food and Drug Branch.

BB — Must pass on 60% of difference between brand name cost and generic cost. Drug

Legend continued on page 74

NABP*LAW* Online Search Terms

Drug Product Selection Laws *(type as indicated below)*

- biosimilar
- "drug product selection"
- formulary selection
- product substitution requirements "narrow therapeutic index"
- substitution authorize requirements
- substitution generic requirements

19. Drug Product Selection Laws (cont.)

LEGEND — cont.

dispensed must be less expensive than drug prescribed.

CC — Prescriber must indicate "brand necessary" or "brand medically necessary" in own handwriting or product selection is allowed.

DD — Patient may request that brand name be dispensed, but prescriber must authorize generic.

EE — Prescriber may indicate orally or in own handwriting "Do Not Substitute" or similar words. Allows use of a preprinted "Do Not Substitute" box, provided that the prescriber personally initials the box.

FF — Prescriber must write "brand necessary," "no substitution," "dispense as written," or "DAW" in own handwriting. (See 18 V.S.A. §4606 Brand Certification.)

GG — Patient may request, in writing, that the brand name be dispensed.

HH — Drug dispensed must be less expensive than drug prescribed.

II — Patient must be informed/notified. (KS – Regulation KAR 68-2-20.)

JJ — Director of Health designates items on Drug Product Selection List.

KK — Positive Formulary and "Orange Book."

LL — Prescriber must write on the face of the prescription in own handwriting the phrase, "Do not interchange."

MM — Formulary commission, a separate Department of Public Health agency, makes those decisions.

NN — But they are still substitutable, it is just not mandatory. There are currently no drugs on the list.

OO — The Board has the authority to publish a list of narrow therapeutic index drugs that cannot be substituted. However, the current list contains no drugs.

PP — Refer to the Department of Health, Food and Drug Branch.

QQ — Refer to KAR 2:116, drug products with therapeutic problems.

RR — State utilizes a negative drug formulary.

SS — Must be therapeutically equivalent as designated by the FDA "Orange Book" ratings. (WI – WI Statute 450.13(1))

TT — The prescriber shall, in the prescriber's own handwriting, include on the prescription the following language (but not limited to): (1) "Brand name medically necessary," "dispense as written," "medically necessary," "brand name," "no generic;" or (2) Any abbreviation of the language in the section above; or (3) Any other prescriber handwritten notation, such as circling a preprinted "dispense as written" on the prescription order, that clearly conveys the intent that a brand name is necessary for the patient.

UU — For narrow therapeutic index drugs only.

VV — May substitute with documented consent of treating prescriber and patient.

WW — If a prescriber orders by any means that a brand-name drug must be dispensed, then no drug selection is permitted.

XX — Can dispense generic epilepsy drugs on the original prescription as long as that brand is maintained. Before the pharmacist can change the brand of the generic, permission must be obtained from the prescriber and the patient.

YY — Except for anti-epileptic drugs (225 ILCS 85/26(c)).

ZZ — A practitioner may specify in writing, by a telephonic communication or by electronic transmission that there shall be no substitution for the specified brand name drug in any prescription. May not use default values on the prescription. For an electronically transmitted prescription, the prescriber or prescriber's agent shall clearly indicate substitution instructions in the prescription drug order as well as all relevant electronic indicators sent as part of the electronic prescription transmission.

AAA — Prescriber must indicate "may not substitute" by marking a designated box. See Section 225 ILCS 85/25.

BBB — Two lines on prescriptions are mandatory. A pharmacist can only substitute if indicated by physician signing that line; however, if a prescription from a practitioner who is located in another state and does not expressly prohibit substitution, a pharmacist is permitted to substitute. Public school employees are exempt from this provision.

CCC — "Brand name medically necessary" shall be handwritten (or printed if electronically generated) on the face of the prescription if it is medically necessary that an equivalent drug product not be selected.

DDD — Product must be A or AB rated as defined by the "Orange Book."

EEE — The Board recognizes the FDA Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") as the basis for the determination of generic equivalency within the limitations stipulated in that publication. Therapeutic substitution is now allowed by regulation effective December 29, 2014.

FFF — Hard copy only. Does not apply to electronic.

GGG — Patient must be notified orally and in writing.

HHH — Interchangeability for biosimilars/ biologics only if approved by FDA.

III — Must obtain prescriber approval to substitute a drug product that is not equivalent.

JJJ — Definition of "biosimilar," "interchangeable," and "reference biological product" in §54.1-3401; allowance in §54.1-3408.4; reference to nonresident pharmacies in §54.1-3434.1; and reference in §54.1-3457.

KKK — Under review.

LLL — Effective September 1, 2015.